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T H E U N I V E R S I T Y O F A L B E R T A

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THE RELATIONSHIPS BETWEEN THE NURSING CARE
OF THE PRETERM NEONATE
AND SELECTED PHYSIOLOGICAL PARAMETERS

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T H E U N I V E R S I T Y O F A L B E R T A

THE RELATIONSHIPS BETWEEN THE NURSING CARE
OF THE PRETERM NEONATE
AND SELECTED PHYSIOLOGICAL PARAMETERS

by



PATRICIA MARY TOMNEY

A THESIS

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES AND RESEARCH
IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE

OF MASTER OF NURSING

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T H E U N I V E R S I T Y O F A L B E R T A
FACULTY OF GRADUATE STUDIES AND RESEARCH

The undersigned certify that they have read, and
recommend to the Faculty of Graduate Studies and Research, for
acceptance, a thesis entitled

THE RELATIONSHIPS BETWEEN THE NURSING CARE
OF THE PRETERM NEONATE
AND SELECTED PHYSIOLOGICAL PARAMETERS

Submitted by Patricia Mary Tomney

in partial fulfilment of the requirements for the degree of
MASTER OF NURSING.



D E D I C A T I O N

To my mother, who understood the dream,
and to my father, who would have been so proud.

ABSTRACT

This exploratory study was undertaken to describe the nature, duration and frequency of nursing care given to the critically ill preterm infant in a neonatal intensive care unit. Relationships were studied between the nursing care and selected physiological parameters. In addition, as part of a concomitant medical research project, a neuro-muscular blocking agent (pancuronium) was administered to each infant, to determine whether skeletal muscle paralysis altered the infant's physiological responses.

A quasi-experimental, equivalent time-samples design was utilized, in keeping with the descriptive nature of the research. The study subjects constituted a population of ten infants who met the criteria of having a gestational age of 37 weeks or less, a birthweight of 801 to 2000 grams, and respiratory distress requiring mechanical ventilation and an inspired oxygen concentration of 40% or greater.

All subjects were studied for a total of 24 hours, 12 hours during which muscle relaxant medication was administered and 12 hours during which no drug was given. Throughout both study periods, all nursing care given to the infants was observed and recorded by the investigator using a continuous observation tool. Physiological parameters were continuously recorded on a four channel recorder.

Analysis of the data revealed a significant reduction in the incidence of hypoxia, hyperoxia, and increased intracranial pressure during the administration of pancuronium. No

relationship was found between the frequency and duration of nursing care and the duration of these physiologic changes. Associations were discovered between physiologic changes and specific categories of nursing care. These relationships varied with the administration or absence of pancuronium.

Although the study was limited in scope, and generalization of the findings was not possible, the results suggest that nursing care can influence the physiological stability of the critically ill preterm neonate. Pharmacologically induced muscle relaxation may assist in diminishing the fluctuations in physiological values which are seen in these infants. These tentative findings present a challenge to nursing practitioners and researchers to evaluate and modify nursing procedures to optimize the infant's physiologic status.

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C H A P T E R I

INTRODUCTION

Statement of the Problem

Various routine procedures are carried out in most nurseries for premature infants. Many of these procedures have never been subjected to critical testing and therefore lack the support of satisfactory evidence of effectiveness...It must be understood that no 'routine' for the care of the premature infant should be regarded as immutable and above criticism.

(Silverman, 1964b, p. 143)

There is growing evidence that seemingly innocuous, routine procedures, employed in the care of the preterm neonate, can have a profound effect on the infant's condition. Changing a diaper has been shown to drop the infant's oxygen tension (PO_2) by as much as 30 torr (Peabody, Willis & Gregory, 1978), and airway suction leads to an average fall in PO_2 of 40 torr (Dangman, Hegyi & Hyatt, 1976). Performing a number of procedures in close succession appears to have an additive effect in producing hypoxemia (Speidel, 1978), and the infant who requires assisted ventilation is more severely affected than his spontaneously breathing counterpart (Huch, Huch & Albani, 1976).

The reason for such precipitous falls in PO_2 is unknown, but has been postulated to result from an increase in right to left shunting in the newborn (Speidel, 1978). Shunting is believed to occur as a result of struggling and crying which is a frequently observed response to handling (Vidyasagar &

Asonye, 1979). If these theories are correct, then diminishing or eradicating the infant's motor response to handling through the use of sedative or muscle relaxant medication should maintain a homeostatic range of oxygenation.

The present study was designed to describe the nursing care given to a group of critically ill, preterm infants, and to explore the relationships between nursing care and selected physiological parameters.¹ A continuous observation technique was used to describe the care given over a twelve hour period, on two consecutive days. The infant's behavioral response to care was also noted during this time. The physiological measures chosen for study were: heart rate, mean arterial blood pressure, intravascular oxygen tension, and intracranial pressure. These parameters were continuously monitored and recorded during the study periods.

During one of the two study periods, determined randomly, a neuromuscular blocking agent was administered to the infant, inducing skeletal muscle paralysis. Data on handling and infant response were compared for the two study periods to explore whether any relationships between handling and response, which occurred during the control period, were altered by muscle relaxation.

¹The present research took place as part of a larger study conducted by Dr. N. Finer, Department of Pediatrics, University of Alberta, to determine the effects of muscle relaxation in the preterm neonate.

Need for the Study

The preterm, low birthweight infant is well known to be at risk for both immediate and long-term developmental problems (Solkoff, Yaffe, Weintraub & Blase, 1969). Many of these problems were discovered, upon further investigation, to be iatrogenic in nature, resulting from well-meaning but potentially harmful efforts to preserve the infant's life (Lucey, Peabody & Philip, 1977). Any procedure which is associated with the fluctuation of vital signs beyond physiological boundaries should be considered in light of its potential risk as well as its assumed benefit to the infant.

Hypoxia, particularly when prolonged or severe, has been reported to be associated with neurologic morbidity (Braine, Heimer, Wortis & Freedman, 1966) and increased mortality rates (Canadian Pediatric Society, 1975). The duration and severity of hypoxia which must exist before sequelae are seen, however, are still unknown. Hyperoxia has been associated with the impaired replication of deoxyribonucleic acid (DNA) (Nelson, 1976), and with the development of chronic lung disease and retrolental fibroplasia (Kinsey, Arnold & Kalina, 1977).

With the exception of a study by Finer and Stewart (1979), the observations of other researchers have not included the continuous measurement of heart rate, blood pressure, or intracranial pressure. Bradycardia, however, has been noted to accompany hypoxia (Dangman et al., 1976) and may further compromise the infant's condition by preventing adequate perfusion of tissues. Hypotension, often secondary to

hypovolemia, occurs frequently in the infant with hyaline membrane disease (Haddock, 1980), and may also interfere with oxygenation at the cellular level. The significance of increased intracranial pressure in the newborn is not well understood, although it has been associated with the occurrence of intracranial hemorrhage in one recent study (Reynolds, Evans & Reynolds, 1979). Intracranial hemorrhage is reported to be one of the leading causes of death in the preterm infant with hyaline membrane disease who requires intermittent positive pressure ventilation (Hambleton & Wigglesworth, 1976).

If struggling and crying are the cause of precipitous falls in PO_2 , as Vidyasagar and Asonye (1979) have suggested, then keeping the infant quiet should reduce the incidence of hypoxia. Diminishing the incidence of struggling and crying would also be expected to stabilize heart rate, blood pressure, respiratory rate and intracranial pressure. A number of authors (Dangman et al., 1976; Speidel, 1979; Strang, 1977) have advocated a "hands off" approach to the preterm infant in order to promote rest and preserve calories needed for growth.

The work of Hasselmeyer (1964) and subsequent nursing researchers (Barnard, 1973; Chapman, 1975; Neal, 1977) clearly demonstrated, however, that planned tactile, vestibular, or auditory stimulation promoted the rate of growth and neurologic development of the preterm infant. Klaus and Kennell (1975) also reported that stimulation promoted the development of parent-infant attachment. Increasing awareness of the effects of handling on the oxygen levels of small babies may cause infants

to be deprived of needed stimulation.

The use of muscle relaxant medication, which eradicates motor response without diminishing sensory perception (Kravitz & Pace, 1979), may well reduce the harmful physiologic effects of handling while maintaining the sensory input from the environment so important to development.

Research Objectives

Specific nursing research objectives were as follows:

1. to describe the frequency, duration, and nature of handling of the critically ill preterm neonate;
2. to describe the infant's response to handling as measured by observed behavior and changes in the physiologic parameters of heart rate, blood pressure, intracranial pressure and intravascular oxygen tension (IVO_2);
3. to explore whether the frequency, duration, and nature of handling is altered when the infant is in a condition of total skeletal muscle relaxation; and
4. to discover whether the infant's response to handling is altered during skeletal muscle relaxation.

Assumptions

Three basic assumptions were essential to the conduct of the study.

1. Handling is necessary to provide optimal care to the critically ill infant.
2. A homeostatic or "steady state" is preferable to the

fluctuation of physiological parameters beyond normal bounds.

3. The administration of muscle relaxant medication is not harmful to the infant.

Other assumptions, which are essential to the conceptual framework of the study, are made explicit in a subsequent section of the paper.

Definition of Terms

The following definitions have been accepted by the investigator for terms utilized throughout the study.

Preterm infant is any infant born before the end of the thirty seventh week of gestation, regardless of birth weight (Korones & Lancaster, 1976, p. 75).

An infant who is appropriate for gestational age (AGA) is one whose rate of growth was normal at the moment of birth. Most preterm infants are AGA (Korones & Lancaster, 1976, p. 96).

An infant who is small for gestational age (SGA) is one whose rate of intrauterine growth was slowed, and whose birthweight was below the tenth percentile for his age. Preterm infants may also be SGA (Korones & Lancaster, 1976, p. 75).

A neonate is an infant who has not yet reached his twenty eighth day of life (Hasselmeyer, 1964, p. 2).

The neonatal period is the period of time from birth to the completion of the twenty seventh day of life (Hasselmeyer, 1964, p. 3).

A neonatal intensive care unit (NICU) is a specialized nursery which provides facilities and trained personnel for the acute care of the critically ill neonate.

In this study an infant who suffers from respiratory distress, requiring mechanical ventilation and an inspired oxygen concentration (FiO_2) of .65 or greater, is considered to be critically ill.

A caregiver is any person, including the infant's parents, nurses, doctors, x-ray and laboratory technicians, who makes purposeful physical contact with the infant.

Handling is the touching, feeling, moving or holding by use of a person's hands or arms, which is directed at another living organism (Hasselmeyer, 1964, p. 3).

The nature of handling refers to the purpose of the physical contact, and a description of the activities performed by the caregiver.

The duration of handling is defined as the time, expressed in minutes, during which the hand or arm of the caregiver is in contact with any part of the infant's body.

The frequency of handling is defined as the number of times that physical contact with the infant occurs, regardless of the duration of the contact.

The infant's behavioral response to care refers to the occurrence of overt bodily behaviors and crying.

Overt bodily behaviors are those activities of an organism which can be observed and recorded by another person (Hasselmeyer, 1964, p. 4).

Crying refers to a state of being in which vocalization may range from a weak, whining sound to a loud, tense and/or forceful yell (Hasselmeyer, 1974, p. 4).

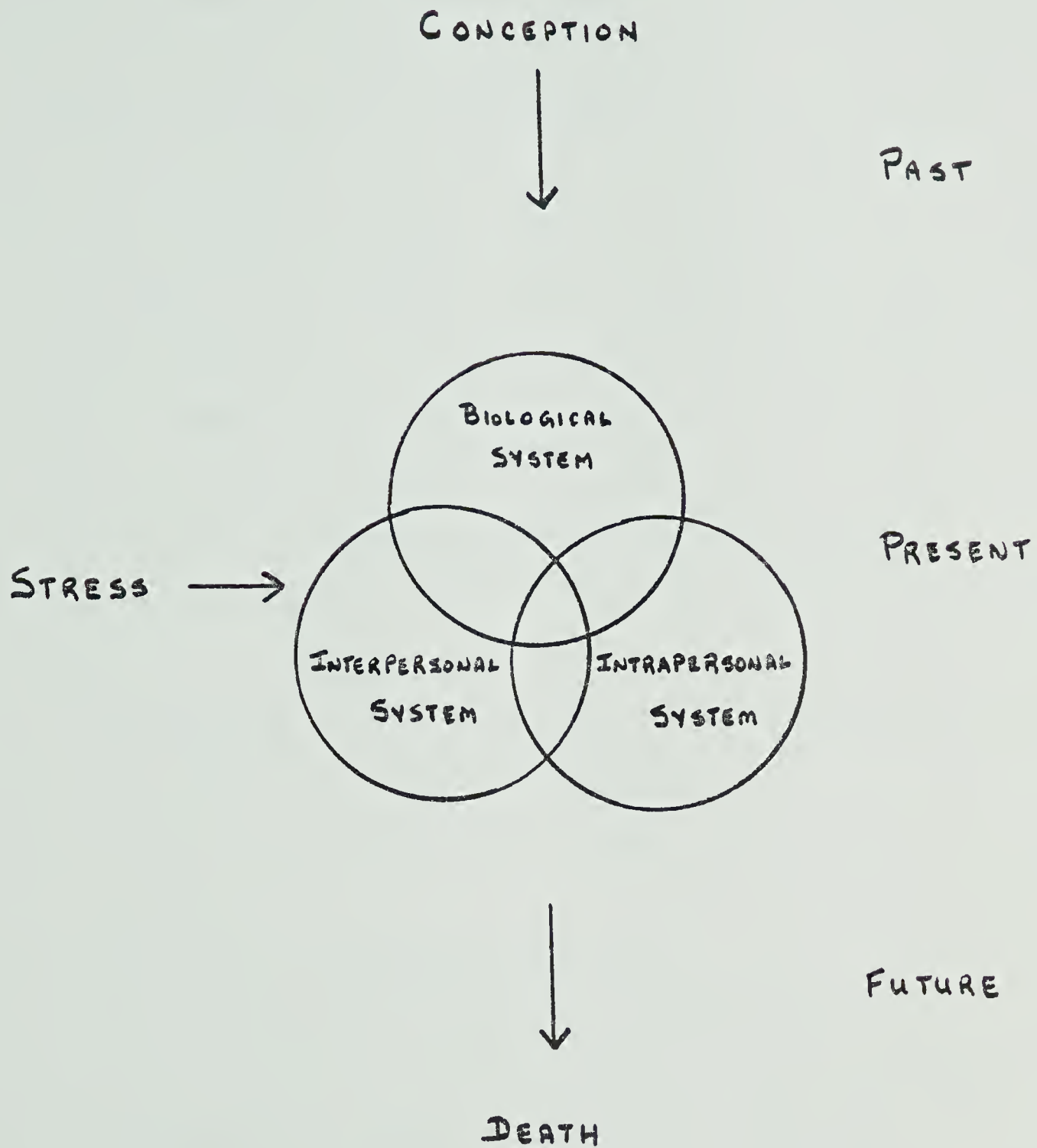
Conceptual Framework

Developmental models are defined as "those bodies of thought that center around growth and developmental change" (Riehl & Roy, 1974, p. 267). A developmental model of nursing was considered to be the most appropriate for the study since many of the problems experienced by the preterm infant are considered to result from his developmental immaturity.

Simple developmental models view the patient as a passive individual and the nurse as an active participant who assists the patient to attain his optimal level of health. This type of model was used by Hasselmeyer (1964) in her study of handling of preterm infants. Interactional models expand on this idea to include the patient and his family as active participants, responsible for their own level of health. An interactional model was used by Barnard (1973) in a study on the effects of stimulation on the sleep behavior of the preterm infant.

The systems-developmental stress (SDS) model created by Chrisman and Riehl (1974) expands the interactional model further by including elements of both systems and stress theory (Figure 1). Using the SDS model, man is viewed as a system, encompassing interpersonal, intrapersonal and biologic components. The human system moves through time, therefore the present, i.e. the time during which nurse-patient interaction

Figure 1 The Systems-Developmental Stress Model



occurs, is seen to be the synthesis of past experience. What occurs in the present time can influence the patient's potential for the future. As man is moving through time, he is also moving through developmental stages, from conception to death. His development depends on a combination of his genetically endowed capacity and his environmentally dictated capability.

The picture of man, created in the SDS model, is similar to an impressionist painting: man is captured in a specific environment, at a specific time and developmental stage, as a pastoral scene may be painted from a particular perspective, with a specific combination of light and shadow. The picture leaves no doubt, however, that change occurs continuously and that things are different as soon as they are captured.

Certain beliefs underlie and give substance to the SDS model.

1. Professional nursing intercedes in the systems-developmental continuum with a therapeutic purpose.
2. Underlying all nursing activity is a caring for the individual.
3. The nurse is the patient's advocate.
4. The nurse supports life and the quality of life.
5. Critical analysis of the patient/client and his condition is accompanied by respect for him as an individual.
6. The patient is an integral part of planning and decision-making.
7. The nurse supports and promotes health.

(Chrisman & Riehl, 1974, pp. 248-9)

When this model is applied to clinical practice, the nurse's role is to analyse the biological, interpersonal and intrapersonal systems of the patient, to observe the interaction of these systems, and to note relationships among the systems, the time, and the environment.

Five assumptions are essential to the understanding and application of the model.

1. Man can be viewed as a set of dynamic systems interacting within an environment and along a developmental continuum.
2. Development includes biologic, interpersonal, and intrapersonal change and each perspective interrelates with every other and influences health.
3. An individual moves along the continuum by a gradual mediation from one developmental state to another.
4. Change is inherent to life. The systems attempt to maintain stability within change.
5. The patient's situation can be described as the interface between the human system and time-environment.

(Chrisman & Riehl, 1974, pp. 250-1)

The functional component of the SDS model is based on a construct of the stress process: the sequence of reactions which occur in response to a stressor. The definition of terms as they are used within the model is critical to an understanding of how they may be applied to a clinical situation:

<u>Stressor</u> -	the precipitating agent which activates the stress process
<u>Stress</u> -	the dynamic force which produces strain or tension within the organism

Stress state - the reactive condition of an organism which occurs as a result of stress

Adaptation - the coping response of the organism to the stress state and/or the stress

Stressed change - the difference in the organism as a result of the stress process and not directly related to the change due to normal development

(Chrisman & Riehl, 1974, p. 251)

The structure and function of the present research can be readily described in terms of the SDS model.

The point in time chosen for observation of the newborn was the early neonatal period, prior to 48 hours of life. The biologic system was chosen as the subject for investigation, since its components were readily measurable and yielded considerable information about the infant. Effects of nursing intervention on the interpersonal and intrapersonal systems of the newborn would require long-term follow-up study, beyond the scope of the present research.

The environment for the study was the NICU, more specifically a radiant warmer unit which left the infants both literally and figuratively open to the environment and subject to change through interaction with their surroundings. The developmental stage of the infants was the newborn stage which was further complicated by the fact that all were prematurely born. The preterm period, from birth until the infant attains 40 weeks post conceptual age has been well described from a developmental point of view, but mainly in respect to biologic systems. The babies were also considered to move through time in the study, and were observed on two consecutive days, under

two environmental conditions. These descriptions of the subjects, the setting and the time reflect the framework or structure of the research, based on the beliefs and assumptions inherent in the model. The functional portion of the model describes the process by which changes in the system can be observed, understood, or influenced.

Each of the newborns in the study was subjected to four major stresses: birth, respiratory distress, assisted ventilation and handling. The stress process for each of these stresses is illustrated in Table 1. The fourth stress, handling, was chosen as the subject for research.

Ethical Considerations

"Ethics is a branch of philosophy which is concerned with thinking about morality and moral judgement" (Overton, 1977). In clinical research using human subjects ethical considerations centre around the potential benefits and potential risks of the research to the individual subject, to a target group and/or to society as a whole. Specific ethical issues in the present study were related to the administration of muscle relaxant medication and to the use of preterm infants as study subjects.

The Medical Research Council has defined research on human subjects to be "research carried out according to a scientifically valid protocol in which human beings are submitted to procedures, the purposes of which may go beyond the subjects' need for prophylaxis, diagnosis or therapy or may invade the subjects' privacy" (1978, p. 7). While the

Table I Stress Process in the Preterm Infant

Stressor	Stress	Stress State	Adaptation	Stressed Change
Preterm birth	Transition to extrauterine life	Lungs responsible for gas exchange	Initiation of respiration Absorbtion of lung fluid Closure of anatomical shunts Prevention of alveolar collapse	Attainment of adult cardio-pulmonary pattern
Hyaline Membrane Disease	Deficiency of surfactant	Alveolar collapse Increased pulmonary vascular resistance Persistent fetal circulation Hypoxia, Acidosis	Tachypnea Grunting Nasal flaring	Increased production of surfactant
Intermittent positive pressure ventilation	Inability to breathe independently	Decreased respiratory rate Tachycardia Hypotension Apnea, Cyanosis	Normal heart rate, respiratory rate and blood pressure No apnea or cyanosis	Normal, independent ventilation
Admission to NICU	Handling	Altered oxygenation Increased intracranial pressure	Increased motility Crying	Homeostatic state

administration of pancuronium was not crucial to the survival of the study subjects, the safety and benefits of its use in neonates had been previously determined (Bennett et al., 1975; Churchill-Davidson & Wise, 1964; Stark et al., 1979). None of these investigators noted side effects in the infants studied. The potential benefits to the preterm infant, in reducing struggling, crying and subsequent hypoxia were considered by the investigators to outweigh potential risks.

The research protocol was also submitted to the Clinical Investigation Committee of the Royal Alexandra Hospital, Edmonton, where the study was to take place. The committee approved both the clinical and ethical aspects of the research.

Preterm infants as minors are considered "incompetent" (Medical Research Council, 1978, p. 12) in that they are unable to give informed consent for their participation as study subjects. In such circumstances, "proxy consent" occurring in two stages is recommended (Medical Research Council, 1978). The first stage involves asking the parent or legal guardian to consent on behalf of the potential subject. Explanations to the parent should include the procedures involved, potential risks and side effects, the nature of the experiment, and the possible benefits to the subject and to others. Anonymity must be ensured and the right to withdraw the subject from the research at any time must be made explicit (Medical Research Council, 1978). The procedure for obtaining consents in the present study is outlined in Chapter III.

The second level of proxy consent is given by a subject

advocate or ombudsman who is an integral part of the hospital in which the research is to be performed (Medical Research Council, 1978).

During this study, the patient's own physician and/or the physician on call for NICU had frequent contact with the study subjects, assessed their conditions, and had the option of discontinuing the study if indicated. In light of the foregoing procedures, the present study was considered by the investigator to meet ethical standards for research.

C H A P T E R I I

Review of the Literature

Literature which is pertinent to the present research has been chosen for review and is presented in three major sections. Studies of handling of the human neonate are discussed in terms of their methodology and general findings. Hypoxia, hyperoxia and increased intracranial pressure are discussed as potentially harmful results of handling. Lastly, two possible ways of minimizing the effects of handling are presented, continuous monitoring techniques and the use of pharmacologically induced skeletal muscle relaxation.

Studies of Handling

Handling has long been considered potentially harmful to the immature, small or sick newborn. In 1945, Mary Crosse, the British authority on care of the premature infant warned that cyanotic attacks were easily precipitated by such procedures as feeding and handling. She also stated "to improve the general condition of the child it must be kept warm, fed correctly, and handled as little as possible" (Crosse, 1945, p. 75). By 1975, in the eighth edition of her book, Dr. Crosse had changed her opinion little. She stated: "apart from any necessary changes in position, the infant should be disturbed as little as possible and all unnecessary nursing procedures should be avoided" (Crosse, 1975, p. 130). Mary Lou Moore (1972), a nursing author, adds

that "a very tiny immature baby should probably be handled as little as possible and certainly in the most gentle way" (p. 145).

The difficulty of interpreting such statements from a clinical nursing viewpoint is that they are so imprecise. What, for example, should be considered an "unnecessary" nursing procedure? Is there scientific evidence to suggest that the infant "probably" should not be handled? What is "gentle" handling and how is it beneficial to the infant?

Although a number of studies on the effects of handling appear in the literature, the majority deal with research on animals. The present discussion will be restricted to those studies dealing with human subjects.

Prior to 1970, only three such studies were reported. The first, reported by Hasselmeyer in 1964, involved the administration of increased tactile and kinesthetic stimulation to preterm infants, challenging the prevalent belief in minimal handling. Sixty preterm infants were randomly selected and randomly assigned to experimental and control groups. The control group received routine nursery care involving about 95 minutes of handling in 24 hours. The experimental group received extra rocking, cuddling and stroking, totalling five hours of handling in 24 hours.

Infants in the experimental group were found to be more quiescent, especially before feeding, while control infants exhibited more crying before feeds. There were no differences between the groups in morbidity, weight gain, number of defecations or response to the interruption of a feeding. Infants

who received routine handling had a higher rate of infection than experimental infants, although the reason for this difference was not adequately explained.

Solkoff, Yaffe, Weintraub and Blase (1969) report a second study of handling, performed by Freedman, Bouerman and Freedman in 1966. The latter group studied five sets of twins, rocking one twin for 30 minutes, twice a day, for seven to ten days, and giving the second twin routine nursery care. The rocked infant gained weight at a greater rate than his control twin in every group, although this trend did not persist.

Thirdly, Solkoff et al. (1969) studied ten low birthweight infants to determine the immediate and long term effects of handling on behavioral and physical development. Experimental infants received five minutes of stroking every hour for a total of ten days, and control infants received only routine nursery care. Handled infants were more active than controls as measured by a stabilimeter and polygraph recordings. They were also observed to cry less than their routinely handled counterparts. Experimental infants regained their birthweights faster but lost their initial advantage by six weeks of age. At seven to eight months of age, a physical examination was performed and the Bayley Test of Motor and Mental Development administered by a pediatrician who had no knowledge of the experiment. Experimental children surpassed controls on both measures. Home visits made at the same time by medical students, who were also not aware of the purposes of the study, revealed that greater stimulation and mother-infant interaction occurred in the

environments of experimental children.

Studies published in the 1970's provided more complex forms of stimulation to the infants, but their results were similar.

Barnard (1973) studied 15 preterm infants with a mean gestational age of 32 weeks and birth weights ranging from 1269 to 2453 grams. The experimental group of seven randomly assigned subjects received kinesthetic stimulation in the form of mechanical rocking, and auditory stimulation in the form of a recorded heart beat, for 15 minutes each hour over a fourteen day period. Experimental subjects showed a greater gain in quiet sleep and a greater drop in the active awake state than did controls. These differences were significant at the .01 and .05 levels respectively using the Student's t test.

Neal (1977) provided various forms of vestibular stimulation to four groups of five preterm infants, ranging in age from 28 to 32 weeks gestation. Birthweights were not specified. Infants in group A were placed in a hammock which was swung for 30 minutes, three times a day; group B infants were placed in a hammock which they could swing themselves by moving; group C infants were placed in a stationary hammock and group D infants were given routine care. The study continued until the infants were 36 weeks of age. The groups were compared on three major variables. Group A had the highest scores for general maturation as measured by the Graham Behavioral Test for Neonates. Group A infants also achieved and maintained a normal pH earlier than infants in other groups. Infants in group B showed the greatest increase in weight gain although this was

not maintained throughout the first year of life.

While all programs described demonstrated some degree of developmental improvement in the experimental groups, none dealt with the critically ill, ventilated neonate during the acute phase of illness. Excessive handling at this time may continue to be harmful.

In one of the few studies that did look at this population of infants, Speidel (1979) found that "any disturbance of these babies, even for the most minor of procedures, often causes a sharp fall in PaO_2 " (p. 284). Usually, the infant recovered spontaneously, but a series of procedures in close succession caused a prolonged fall in PaO_2 . Speidel also found movement, struggling, and crying to cause irregular respirations, slight tachycardia, and a marked fall in PaO_2 . He concluded that this resulted from a right to left shunt via the foramen ovale and patent ductus arteriosus.

In an early study by Harrison, Heese and Klein (1968), the investigators found that crying increased PaO_2 in infants during the acute stages of HMD. This is in contrast to the work of other researchers who found PaO_2 to fall during crying in normal infants less than four days old (Prec & Cassals, 1976) and in infants recovering from respiratory distress (Dinwiddie, Patel, Kumar & Fox, 1979). Huch, Huch and Rooth (1973) further suggested that brief but intense crying might decrease PO_2 as a result of ineffective ventilation as well as shunting. Ventilation perfusion abnormalities, due to the large intrathoracic pressure changes during crying, have also been suggested as a causative

factor (Dinwiddie et al., 1979).

Dangman et al. (1976) found that in sick newborns at rest, with normal heart rate and respiratory patterns, the PO_2 normally varied by ± 15 torr. PO_2 was reduced an average of 30 torr during "routine care", 40 torr during airway suction, and 50 torr during crying. Bradycardia, which often accompanied the fall in PO_2 , was much more transient than hypoxemia, which persisted for as long as seven minutes before returning to baseline values. Dinwiddie et al. (1979) found hypoxemia to last up to 12 minutes following the cessation of crying.

Effects of Handling

Hypoxia

The normal blood PO_2 of a full term newborn ranges from 80 to 100 torr. In the preterm infant it is slightly lower, being 40 to 80 torr in post ductal samples. Clinically, the preterm infant's O_2 is maintained within the range of 50 to 70 torr to provide adequate oxygenation of tissues (Finer & Stewart, 1977). An inadequate PaO_2 , anything less than 50 torr in the preterm infant, is referred to as hypoxemia and the resulting lack of oxygen supply to the tissues as hypoxia (Shapiro, Harrison & Walton, 1977). Hypoxia in the newborn is of grave concern to clinicians because of the immediate and long term effects of hypoxia on the body.

It has been indicated by Friedman (1972) that the fetus can respond with both direct and reflex physiologic mechanisms to mild asphyxia. The primary response is an increase in heart

rate, a small rise in arterial pressure, and a redistribution of cardiac output to the placenta, heart and brain, at the expense of skeletal muscle, kidneys, gastro-intestinal tract and lungs. These effects are believed to be due to increasing baroreceptor and chemoreceptor control, as well as to release of catecholamines into the plasma (Strang, 1977).

During the first five days of life, the healthy full-term newborn responds to a PaO_2 of less than 80 torr with hyperventilation and tachycardia during the first minute of hypoxia, followed by decreasing ventilation over the next two to three minutes of hypoxia (Brady & Ceruti, 1966). The initial hyperventilation, resulting in a drop in PCO_2 has been hypothesized as the cause of hypoventilation. When PCO_2 was increased during hypoxia, however, the hypoventilation continued, suggesting that hypocapnia does not adequately explain the ventilatory response of the newborn to hypoxia (Brady & Ceruti, 1966). After the first week of life, the newborn demonstrates and maintains an increase in ventilation during hypoxia which is potentiated by the addition of CO_2 to inspired air. Brady and Ceruti suggested that the transient alteration of response during the first week was due to the presence of a functionally patent ductus arteriosus with right to left shunting during hypoxia.

In the preterm infant, the response to hypoxia remains paradoxical for about three weeks (Bryan & Bryan, 1979). When the preterm infant is challenged with hypoxia, ventilation increases within 30 seconds suggesting that the peripheral

chemoreceptors are intact but then decreases within 5 minutes further suggesting that the peripheral effect is later over-ruled by the central depressant effect of hypoxia. This pattern is known as a biphasic response (Rigatto, 1979). It does not alter with gestational age, but it does with post natal age. By 18 days of age, preterm infants have been shown to respond to hypoxia with sustained hyperventilation.

The preterm infant's response to CO_2 also differs from that of the fullterm newborn. The more immature the infant, the less sensitive he is to the stimulus of CO_2 , which normally increases the ventilatory rate. Additionally, hypoxia has been found to further depress the CO_2 response, in direct contrast to the normal adult response (Rigatto, 1979). The cause of the altered response is believed to be central in origin due either to poor dendritic synapsis in the central nervous system (Rigatto, 1979) or to increased cerebral blood flow which reduces the level of CO_2 in cerebral vessels (Bryan & Bryan, 1979). Bryan and Bryan (1979) also state that the response to increasing hydrogen ion (H^+) concentration in the cerebral spinal fluid is destroyed by hypoxia in the preterm infant, removing another stimulus to respiration.

Hypoxemia in the preterm infant is believed to be caused mainly by the shunting of blood from the venous to the arterial side of the circulation. Shortly after birth this occurs via the foramen ovale and patent ductus arteriosus. Later, it more commonly occurs at a pulmonary level, resulting from the perfusion of atelectatic areas of the lung (Comroe, 1975). In

addition, decreased arterial oxygen concentration has been demonstrated to raise pulmonary vascular resistance, reducing perfusion of the lung and keeping the ductus arteriosus open. Heymann and Hoffman (1979) found that the greater the degree of hypoxia, the more rapid the rise in pulmonary vascular resistance. When hypoxemia was also combined with acidemia, the increase in pulmonary vascular resistance occurred more rapidly. Increasing gestational age was also directly related to increasing pulmonary vascular resistance.

Clinical signs of hypoxemia in the newborn, such as acidosis, hypothermia and apnea, tend to be non-specific. Cyanosis is also an unreliable clinical sign of hypoxia since it does not appear until the PO_2 reaches a dangerously low level due to the shift of the oxyhemoglobin dissociation curve to the left. Since the newborn, and particularly the prematurely born, has a predominance of fetal hemoglobin (HbF) over adult hemoglobin (HbA), the affinity of the infant's hemoglobin for oxygen is much higher (Comroe, 1975). While this affinity is advantageous in enhancing oxygen uptake at the alveolar level, fetal hemoglobin releases oxygen slowly at the cellular level where it is necessary for utilization by the tissues. As a result, the hemoglobin remains highly saturated, and the infant's colour remains pink although he may not be receiving sufficient oxygen to meet his metabolic needs. There is little change in skin colour until hemoglobin saturation falls below 80% and central cyanosis usually indicates a PaO_2 well below 40 torr (Korones & Lancaster, 1976). Generalized cyanosis then, is an ominous and

conclusive indicator of profound hypoxia.

Two factors which can influence the infant's oxygen level are body temperature and sleep state. A neutral thermal range has been defined as "the span of temperature change within which the infant, when asleep, has his lowest O_2 consumption (or heat production) while maintaining a normal body temperature" (Strang, 1977, p. 223). The smaller and younger the baby, the higher and more restricted is the range within which a neutral thermal environment is achieved.

Silverman (1964a) found that when an infant's skin to colon temperature gradient was less than 2°C his metabolism was minimal and that if the gradient was further reduced to 1°C or less, oxygen consumption also became minimal. When an infant becomes cool, his metabolic rate rises and his oxygen consumption is increased (Oliver & Karlberg, 1963). In addition, cooling has been shown to depress the preterm infant's response to hypoxia as he shows no initial hyperpnea, and ventilation is decreased from the outset (Bryan and Bryan, 1979). Cold stress also predisposes the small preterm infant to acidosis, hypoglycemia and other attendant problems.

A second factor which has been found to influence hypoxic response is the sleep state. Martin, Okken and Rubin (1979) established that PaO_2 was significantly lower during active (REM) sleep. Earlier studies had demonstrated that the respiratory depression resulting from hypoxia in the preterm infant eventually induced periodic breathing and apnea (Rigatto & Brady, 1975; Rigatto, de la Torre Verduzco, & Cates, 1975).

Further studies showed that apnea occurred largely during REM sleep, the predominant sleep state in the preterm infant (Gabriel, Albani & Schulte, 1976). The study by Martin et al. (1979) showed that the fall and fluctuations of PO_2 during REM sleep were equally prominent in the presence or absence of apnea. They concluded that the greater variability of PaO_2 in active sleep was due to a continuously changing respiratory rate and tidal volume.

Prolonged hypoxemia has been associated with increased neonatal mortality, and long-term neurologic morbidity (Canadian Pediatric Society, 1975). In a study of 351 prematures, Braine, Heimer, Wortis and Freedman (1966) showed that the degree of hypoxia correlated negatively with birthweight: the smaller the infant, the greater the degree of hypoxia suffered. In addition, the more premature infants showed a greater insult as a result of the hypoxic episodes. Hypoxia was related to both weight loss and infection in the neonatal period and was associated with lowered motor and cognitive test scores throughout the first 14 months of life. These changes could not be accounted for on gestational age alone but resulted from an interaction effect of prematurity and hypoxic insult. Male infants were significantly inferior to females of the same birthweight on both mental and motor tests.

Late hypoxia, occurring after the fifth postnatal day, was the most accurate predictor of poor development during the first year of life. Hypoxia was clearly shown to cause impairment of gross motor function soon after birth and of cognitive function at

seven and thirty weeks. Weakness on cognitive testing related mostly to tasks requiring visual acuity or eye-hand co-ordination and may suggest either that hypoxia has a direct effect on the development of vision or that the injudicious use of oxygen in the nursery may have created harmful levels of oxygen in the blood.

Hyperoxia

Hyperoxia, defined as a PaO_2 greater than 70 torr in the normal newborn, may be as harmful as hypoxia. Excessive concentrations of oxygen in the blood may lead to damage of the brain, lung, eye, red blood cell and testis by impairing the synthesis of DNA and interfering with enzyme functioning (Nelson, 1976). Effects on the eye and the lung have been most thoroughly documented.

The relationship between oxygen and retrolental fibroplasia (RLF) is not clearly understood. The degree of damage appears to depend on the degree of retinal immaturity, the PaO_2 , and the duration of exposure to an increased PaO_2 . Early investigators were unable to demonstrate a relationship between a high PaO_2 and eye damage (Kinsey et al., 1963) but this may be explained by the use of intermittent blood gas sampling which has been shown to miss the fluctuations of PaO_2 evident with continuous monitoring. Despite improved research techniques the association between PaO_2 and RLF is at best erratic and further studies are needed. The incidence of RLF in preterm infants receiving oxygen therapy for respiratory distress syndrome has remained at 1 to

2% since the 1960's (Nelson, 1976).

Bronchopulmonary dysplasia (BPD) or "respirator lung" has also been associated with excessive oxygen therapy in infants receiving mechanical ventilation. Stage I, the exudative phase, occurs at two to three days of age and is characterized by desquamation of alveolar epithelium and loss of bronchiolar ciliary cells. Stage II, the proliferative phase, is marked by opacification of the lungs and occurs on about the fourth day. By ten days, Stage III begins with cystic changes in the lungs and hyperplasia of the type II alveolar cells which are responsible for the production of surfactant. Stage IV is reached at about 30 days when the lungs become hyperinflated, with marked hypertrophy of bronchiolar muscle (Northway, 1967).

The dosage of oxygen necessary to produce Stage IV BPD is reported to be more than 60% for greater than 4 to 5 days (Nelson, 1976). This may occur even in the absence of any ventilatory support.

The immediate effect of high inspired oxygen concentrations is to induce vasoconstriction and alveolar edema. Increased PO_2 interferes with cellular division, impedes the discharge of mucus and stops ciliary transport by the tracheal epithelium. In the long term, this results in fewer alveoli in the developing lungs.

Prolonged mechanical ventilation (greater than six days) with high peak airway pressures (greater than 40 to 60 cm H_2O) appears to contribute to the development of BPD. The use of negative pressure ventilation rarely results in BPD (Outerbridge, 1979), and the addition of positive end expiratory pressure

(PEEP) to positive pressure ventilation has noticeably reduced the incidence of this condition.

Increased Intracranial Pressure

While achieving an adequate level of oxygenation in the systemic circulation is extremely important, it is also essential that the oxygen reach vital centers in order to maintain life. An adequate blood supply to the brain depends largely on the cerebral perfusion pressure (CPP), defined as "the difference between mean venous and mean arterial pressures" (Reynolds, Evans, Reynolds, Saunders, Durbin & Wigglesworth, 1979, p. 170). From a clinical perspective, this value may be determined by calculating the difference between the mean arterial blood pressure (MABP) and the intracranial pressure measured at the anterior fontanelle. The latter measurement has recently been achieved in the newborn by placing a fiberoptic sensor on the anterior fontanelle, from which all hair has been removed. The sensor then notes any changes in pressure within the venous pool which lies directly below the fontanelle, and this pressure is expressed in digital form on a bedside monitor.

Intracranial venous pressure (ICVP) represents "a summation of residual perfusion pressure, gravitational forces, venous volume and venous compliance" (de Lemos & Tomasovic, 1978, p. 398). The normal ICVP in the newborn is 8 to 12 cm H₂O. This pressure increases with acute hypercarbia and crying and decreases with hyperventilation. It is also sensitive to positional changes of the infant (Vidyasagar & Raju, 1977).

The measurement of intracranial pressure in the newborn has become of increasing interest to clinicians because of a possible relationship between raised intracranial pressure and intraventricular hemorrhage.

Subependymal and intraventricular hemorrhage is a frequent cause of death in the premature newborn. In survivors, intracranial hemorrhage has been linked with varying degrees of residual neurologic dysfunction (de Lemos et al., 1978).

Most investigators agree that the sequence of events leading to hemorrhage includes an original hypoxic or hypercarbic insult followed by cerebral arterial or venous hypertension with consequent rupture of fragile cerebral capillaries. One recent study, however, demonstrated that asphyxia alone did not cause an increased incidence of intracranial hemorrhage when compared with control fetuses (Reynolds et al., 1979). The investigators found that the combination of asphyxia with intermittent increases in intracranial pressure greatly increased the incidence of hemorrhage. They suggested that the hemorrhage might be due to increasing pressure in a vascular bed already dilated and damaged from the hypoxic insult. Although this investigation was carried out using exteriorized sheep fetuses, the researchers adequately demonstrated the similarities in the germinal layer of the brain between the sheep fetus at 58 to 85 days gestation and the human infant at 28 to 30 weeks gestation.

A second factor which is associated with intracranial hemorrhage in the preterm infant is mechanical ventilation. The

effects of assisted ventilation on cerebral blood flow and blood volume include the transmission of positive pressure to the thorax, thereby reducing venous return to the heart and the presence of air leaks which can cause venous obstruction and reduce cardiac output. In addition, assisted ventilation can cause rapid fluctuations in PCO_2 which, in turn, alter cerebral blood flow (de Lemos, 1979). When an infant, particularly one requiring ventilatory support, is extremely active with struggling and/or crying, his airway pressure and intrathoracic positive pressure rise. This can result in both disruption of ventilation with possible hypoxia and intracranial venous hypertension since cerebral venous return is compromised. This combination, as demonstrated by Reynolds et al., (1979) may predispose the infant to intracranial hemorrhage.

Minimizing the Effects of Handling

Continuous Monitoring Techniques

In order to detect and treat hypoxia and hyperoxia in the acutely ill newborn with respiratory problems, the measurement of blood gases is essential (Boyle & Oh, 1978). Obtaining blood samples by the intermittent puncture of brachial, radial, temporal or digital arteries is time consuming for staff, painful for the infant, and may be unreliable if the infant is disturbed (Corbet & Adams, 1978). Arterialized capillary blood can also be unrepresentative of arterial blood (Huch et al., 1976). With the recent development of reliable methods of continuous PO_2

monitoring, a constant evaluation of oxygenation is now available.

The instrument system that measures PO_2 has three components: a transducer which senses physiologic information and converts it into a measurable form or signal, a signal processor or conditioner which amplifies or modifies the primary signal, and a display or readout device which presents the output measurement (Heuther, 1978).

The transducer is a modified Clark electrode, consisting of a platinum cathode and a silver anode, covered with a membrane permeable to oxygen. Its function depends on the electrochemical principle that oxygen, in solution with water at a metal surface, will be reduced by the passage of a low voltage current through that solution. The voltage, applied between the anode and cathode, which is necessary to reduce the oxygen in the solution, is proportional to the partial pressure of oxygen in the blood. The Clark electrode may be used on the skin surface, or at the tip of an umbilical artery catheter.

Using the transcutaneous ($tcPO_2$) method, the electrode is attached to the skin with an adhesive ring, and is heated to a temperature of $44 - 45^{\circ}C$. The resultant local hyperthermia and vasodilatation "arterializes" the capillary layer under the electrode (Huch et al., 1976). Molecular oxygen diffuses according to its pressure gradient from the capillaries to the cathode where it is reduced (Rooth, 1978).

Changes in tissue oxygen tension cause proportional changes in electrode current, which is then altered by the

signal processor to a PO_2 value recorded, in digital form, on a display at the bedside. Through the technology of digital-to-analog conversion, it is also possible to obtain a continuous strip recording of changes in PO_2 .

Several investigators have attempted to establish the reliability of $tcPO_2$ measurements in reflecting arterial PO_2 . It is important to note that the values are not identical since oxygen consumption by the mitochondria of the skin, as well as by the electrode itself, tend to lower the PO_2 . This effect is counteracted somewhat by the heating of the electrode since hyperthermia causes a shift of the hemoglobin dissociation curve to the right (Shapiro et al., 1977). In other words, heating alters the normal relationship between hemoglobin saturation and oxygen tension, in this case increasing the PO_2 (Rooth, 1975).

Despite these limitations in the method, the regression co-efficients between $tcPO_2$ and PaO_2 are high, ranging from 0.94 (Huch et al., 1976) to 0.986 (Peabody et al., 1978). One investigator (Clarke, 1978) found a comparatively low correlation of 0.74 but he attributed his poor results to technical problems related to calibration of the monitor and application of the skin electrode.

Alternately, the Clark electrode may be placed in the tip of an umbilical artery catheter, giving continuous readings of PaO_2 in the descending aorta. This method of monitoring has been shown to be accurate and to require less frequent calibration than $tcPO_2$ monitoring (Finer & Stewart, 1979). Thromboses and infection have been reported as complications of

the indwelling catheter (Tooley, 1970).

In one recent study, Conway and his group (1976) demonstrated the use of a catheter tip electrode in a group of newborns with severe respiratory illness. A high correlation ($r = .93$) was found between monitor readings and arterial PO_2 , and few complications were associated with the presence of the catheter. The investigators stated that continuous PO_2 readings allowed precise control of FiO_2 and appropriate changes in ventilator settings. On a number of occasions a drop in PO_2 gave early warning of problems such as a blocked endotracheal tube or pneumothorax.

Skeletal Muscle Relaxation

Pancuronium bromide (Pavulon, Organon) is a non-depolarizing, neuromuscular blocking agent which has been used extensively in adults to produce skeletal muscle relaxation during anaesthesia and mechanical ventilation (Kravitz & Pace, 1979). More recently, its value in the management of mechanically ventilated neonates has been recognized since pancuronium has been shown to improve ventilation and oxygenation and to lower the incidence of pneumothorax (Stark, Bascom & Frantz, 1979).

Pancuronium is a curariform drug, believed to act primarily at the post-junctional membrane, although it also appears to have some inhibitory effect on the pre-synaptic output of acetylcholine (Speight & Avery, 1972). It has no hormonal activity, and does not cause the release of histamine.

In adults, slight increases in heart rate and blood pressure occur transiently, lasting for 10 to 20 minutes following the administration of the drug. It is not known whether this is due to a selective, cardiac vagolytic action or to a release of endogenous catecholamines (Speight & Avery, 1972). These side effects have not been observed in infants (Bennett, Ramamurthy, Dalal & Salem, 1975). Other side effects which have occurred occasionally include skin rash, and an increase in pharyngeal and tracheal secretions.

The neonate is particularly sensitive to the action of non-depolarizing drugs, and has been compared, in this respect, to the patient with myaesthesia gravis (Bush & Stead, 1962). This sensitivity decreases with age, and at one month the neuromuscular response is similar to that of an adult. The cause of such hypersensitivity is not known but is thought to be due to a deficiency in the formation or release of a transmitter substance (Churchill-Davidson, 1964) or to differences in protein binding, altered response of the motor end-plate, or the presence of pre-junctional receptors (Bennett et al., 1975).

Sensitivity to pancuronium is further increased by prematurity, acidosis, hypothermia, and the administration of antibiotics, particularly gentamycin and kanamycin (Bennett et al., 1975). These factors must be taken into account when determining the appropriate dosage of the drug to be administered to the critically ill preterm neonate.

The recommended dosage is 40 to 100 mcg/Kg to achieve paralysis, followed by a maintenance dose given every 50 to 90

minutes for evidence of spontaneous movement or breathing. The onset and duration of action are dose dependent, with the onset varying from 30 to 60 seconds, and the duration from 50 to 90 minutes in the newborn (Bennett et al., 1975).

The metabolism of pancuronium is not yet fully understood in humans. Studies with radioactive pancuronium in dogs showed 33 to 62% of the administered dose to be excreted in the urine within three hours. The remaining drug is then metabolized in the liver, and its metabolites excreted in feces. (Organon Canada Ltd., 1977).

Toxic effects of pancuronium have not been reported in newborns, even when it was administered continuously for seven days (Stark et al., 1979). There were no infants in Stark's study who could not be weaned from the ventilator after receiving a course of the drug.

The effects of pancuronium may be terminated by stopping further administration and allowing the drug to be excreted from the body. If desired, the effects can also be reversed by the administration of atropine 0.08 mcg/Kg followed by neostigmine 0.018 mcg/Kg (Bennett et al., 1975). Neostigmine is an anticholinesterase drug which increases the amount of acetylcholine at the motor end-plate and thereby restores neuromuscular transmission. Atropine is used for its vagolytic action in preventing bradycardia, excessive salivation and bronchorrhea (Kravitz & Pace, 1979).

Nursing care for the infant who is receiving pancuronium is critical to the patient's survival. Should the ventilator fail

to function or become inadvertently disconnected from the infant, he is unable to breathe on his own. The nurse must be particularly observant of the respiratory rate, the ventilator settings, and the condition of the patient. Alarms on the ventilator should always be turned on. A resuscitation bag and mask must be at the bedside at all times in case of emergency.

Suctioning should be performed more frequently than usual since pancuronium increases both pharyngeal and tracheal secretions. Instillation of normal saline prior to suctioning may facilitate the procedure by reducing the tenacity of secretions. In some instances, chest physiotherapy and postural drainage may be of benefit.

Attention must be paid to the infant's patterns of elimination. Although pancuronium does not affect the smooth muscle of the urinary bladder, the periodic, manual expression of urine does appear to be necessary for the newborn. The muscles of the anal sphincter are paralysed by the drug, therefore the nurse may need to assist with bowel evacuation if the infant is being fed.

Skin breakdown can occur rapidly due to the fragility of the preterm infants skin, and his inability to move. This may be further aggravated in the ill newborn if his peripheral perfusion is poor. Curarized infants should be repositioned at least every hour.

The blink reflex is absent when an infant is on pancuronium leading to drying of the cornea. Artificial tears and the application of eye patches help to maintain corneal

integrity.

Although the infant has no control over motor function, his sensory perception remains intact, and his level of consciousness is not altered by pancuronium (Speight & Avery, 1972). This should be remembered when the nurse is performing procedures that may be distressing or painful to the infant. Occasionally sedation is ordered in conjunction with pancuronium (Krauitz & Pace, 1979). Parents, who may already be upset about the infant's condition, may need reassurance that it is still important to touch and talk to their child. They may become discouraged by the lack of response to their handling and visit the NICU less often. The nurse can play a crucial role in maintaining and promoting parent-infant attachment in these circumstances.

Summary of Literature Review

In conclusion, planned programs of tactile, vestibular or auditory stimulation have been demonstrated to improve the rate of weight gain and neurological development in the healthy preterm infant. Even minimal handling of the ill preterm neonate, however, has been shown to alter the infant's level of oxygenation.

Hypoxia and hyperoxia have been shown to be potentially harmful to the infant's immediate condition and long term development, affecting motor and cognitive functioning for the first year of life. Increased intracranial pressure, while less well investigated, has been associated with the occurrence of

intracranial hemorrhage.

Continuous monitoring techniques for PaO_2 should improve awareness of the effects of nursing procedures on the infant, allowing modifications of care as indicated. Skeletal muscle relaxation is one possible means of reducing alterations in oxygenation and intracranial pressure when handling of the infant is necessary.

CHAPTER III

METHODOLOGY

The Research Design

This investigation was an exploratory study to describe the handling received by the critically ill preterm neonate being cared for in a neonatal intensive care unit. The infant's behavioral and physiological response to handling was observed during a period of muscle relaxation with pancuronium bromide and during an equal time period when the drug was not being administered.

The format of the study was a quasi-experimental, equivalent time-samples design, as described by Campbell and Stanley (1963). Observations made during the control period when pancuronium was not administered provided baseline values against which to compare the effects of the experimental variable, i.e. the administration of the drug. The design may be depicted as follows:

Group 1 (n = 5) $X_0 O$ $X_1 O$

Group 2 (n = 5) $X_1 O$ $X_0 O$

where: X = experimental variable

X_1 = experimental variable present

X_0 = experimental variable absent

O = observation and measurement

A research design is considered to have internal validity if it permits distinctions between the effects of the experimental variable and effects associated with extraneous, uncontrolled variables (Campbell & Stanley, 1963). Four factors were considered to have the potential for jeopardizing the internal validity of this study:

1. history;
2. maturation;
3. instrumentation; and
4. selection.

History refers to "the specific events occurring between the first and second measurement in addition to the experimental variable" (Campbell & Stanley, 1963, p. 5). Examples of such events, in this instance, would be changes in ventilatory settings, the administration of sedative medications, or other forms of medical therapy which could cause changes in the infants' behavioral responses or physiological parameters, not attributable to skeletal muscle relaxation. Since this was a clinical trial, using critically ill subjects, necessary changes in medical therapy could not be controlled, and history remained a potential source of internal invalidity.

Maturation refers to "processes within the respondents, operating as a function of time per se" (Campbell & Stanley, 1963, p. 5). Hyaline membrane disease, which affected nine of the ten study subjects, is a time-limited disease which tends to worsen with 72 hours, and run its course in three to five days (Korones & Lancaster, 1976). The stage of the disease process

during which an infant was studied as well as changes due to normal growth and development could therefore have influenced the outcome variables of the study. The division of the population into two groups by random assignment such that one group experienced the control condition first, and the other experienced the experimental condition first, was assumed to overcome invalidity due to maturation.

Instrumentation includes "changes in the calibration of a measuring instrument or changes in the observers" (Campbell & Stanley, 1963, p. 5). The instruments used to measure physiologic parameters were calibrated prior to each study period and as necessary following the reapplication of leads. In addition IVO_2 was compared with blood gas values drawn from the umbilical artery catheter during the study. Changes in observers were minimized by using only one nursing observer for all the study periods. Difficulties in this technique are discussed in the presentation of the nursing observation tool.

Finally, selection formed a source of internal invalidity since three infants were considered to require pancuronium to stabilize their clinical condition and could not ethically be subject to randomization.

External validity refers to the generalizability of the results of the study to other populations or settings (Campbell & Stanley, 1963). In this study, the small number of babies observed, and the difficulties in random assignment, limit the applicability of the findings to the study population. These factors will be discussed more fully in the section on

methodological limitations.

Criteria for the Study Population

The study population consisted of ten preterm infants who were admitted to the Royal Alexandra Hospital NICU, between October, 1979 and January, 1980 and who met the study criteria. Criteria selected for the study included specific demographic characteristics, clinical condition and monitoring capabilities as outlined below.

Only preterm infants were to be included since they were, as a rule, more acutely ill than full term infants and therefore likely to receive more nursing care. Those infants with birth weights between 801 and 2000 grams were chosen since infants 800 grams or less frequently require pancuronium for several days and could not be subjected to a randomized trial of the drug. Conversely, because those infants over 2000 grams rarely require muscle relaxation, administering it for study purposes could not be justified.

Infants who were less than 48 hours of age were chosen in an effort to diminish variation due to the disease process itself. Respiratory distress requiring mechanical ventilation and an FiO_2 of .4 or greater were determined to be the clinical criteria for study subjects to be considered critically ill. Patients requiring mechanical ventilation were studied because this population appeared to have more spontaneous alterations in gas exchange and ICP. It was also considered necessary for all infants to have an umbilical artery catheter with a polarographic catheter

tip electrode in place to provide continuity and consistency in the measurement of PO_2 .

Conduct of the Study

When infants who met study criteria were admitted to NICU, they were assessed and their conditions stabilized by the medical and nursing staff. Written, informed consent was obtained from the parents prior to initiation of the study (Appendix I). It was emphasized that refusal to participate in the study would in no way alter the care received by the baby and that parents were free to withdraw the infant from the study at any time. It was also explained that if there were any clinical indications for or against the administration of the drug, these would be heeded, regardless of the study protocol. Parents were invited to be present during the study and were encouraged to ask questions regarding their infant's response to the medication. All parents agreed to allow their baby to participate in the study.

The order of the experimental and control periods was randomized when possible by selecting one of a group of sealed, shuffled envelopes containing instructions for the conduct of the study. Three infants were considered by the medical staff to require pancuronium during the first time period, therefore random assignment did not occur. In these instances, the appropriate envelope was removed from the remaining envelopes.

All subjects were studied for a 24 hour period, 12 hours under each of the experimental and control conditions, with a 12 hour interim period during which no observations were made.

The experimental condition consisted of the administration of pancuronium bromide 100 micrograms per kilogram (mcg/Kg) to achieve muscle relaxation, followed by a maintenance dose of 70 mcg/Kg, given every 60 to 90 minutes for evidence of spontaneous movement or breathing. At the end of the 12 hour study period, reversal of the effects of pancuronium was achieved with atropine 0.08 mg/Kg followed by neostigmine 0.018 mg/Kg. All drugs were administered through the umbilical artery catheter.

The control condition was similar to the experimental condition in all respects other than the administration of pancuronium. Sedative medications such as chloral hydrate and phenobarbital, which were considered beneficial for the stabilization of the infant's condition, were also given as necessary and would be expected to modify the infant's response to handling.

The Immediate Environment

All infants were nursed on overhead radiant warmer beds, with their skin temperature maintained at 36.8°C by servo-control. Nasotracheal intubation was performed by medical staff using a 3.0 to 3.5 mm Portex tube. Nine infants received assisted ventilation via a Baby Bird ventilator. The tenth baby had a Sechrist ventilator which was in the unit at the time for evaluation by the staff. Peak inspiratory pressures, positive end expiratory pressures, ventilatory rates and inspiratory times were individually determined for each infant, based on blood gas

results.

Fluids and electrolytes were administered to the infants via an umbilical artery catheter. Some infants also had a peripheral intravenous for the infusion of blood or blood products. Three infants had bilateral chest tubes attached to Gomco suction.

The nurse patient ratio for the study subjects was usually one to one. Occasionally, when the unit was short staffed, the nurse was also caring for a second baby. Other nurses in the unit performed necessary tasks when the infant's nurse went for lunch and coffee breaks. The nurses worked 12 hour shifts.

Other staff who had contact with the infants during the study included physicians, respiratory therapists, x-ray technicians and a physiotherapist. The parents of all the infants, except the one infant who was transported to the unit, also visited during the study period.

Measurement

Data were collected on four physiologic parameters: heart rate, blood pressure, intravascular oxygen level, and intracranial pressure (ICP). With the exception of the ICP sensor, all monitoring devices are used routinely in the care of the critically ill neonate.

Heart rate was measured using self-adhesive chest electrodes attached to a bedside monitor (Model 78330A or Model 78342A, Hewlett Packard, Waltham, Ma.) which displayed the mean apical rate and the electrocardiogram. Alarms were set at 100 beats per minute (low) and 200 beats per minute (high).

Mean arterial blood pressure and intravascular oxygen tension were obtained through a #4 or #5 umbilical artery catheter, with a polarographic catheter tip electrode (G. D. Searle, Buchs, England), inserted to the level of the eighth thoracic vertebrae. Blood pressure was monitored using a transducer (Model 1280, Hewlett Packard, Wartham, Ma.) attached to the umbilical artery catheter. Values for blood pressure and IVO_2 were continuously displayed on bedside monitors (Model 7834A, Hewlett Packard, Waltham, Ma., and G. D. Searle, Buchs, England) as well as being recorded on a four-channel recorder (Model 7404A, Hewlett Packard, Waltham, Ma.). Alarms for IVO_2 were set at 50 torr (low) and 75 torr (high) during the study periods.

Intracranial pressure was measured by means of a fiberoptic sensor (Model 10004, Ladd Research Industries, Burlington, Vt.). Placement of the sensor necessitated the shaving of a small area over the anterior fontanelle. Intracranial pressure and heart rate were also continuously recorded on the four channel recorder at the bedside.

Respiratory data, including arterial blood gas values, inspired oxygen concentrations and changes in ventilatory therapy as well as the infants' date of birth, birth weight, gestational age and Apgar scores were also recorded.

The Nursing Observation Tool

While a number of tools for measuring nursing activities in a patient unit exist (U.S. Department of Health, Education, and

Welfare, 1964), only two were discovered which dealt specifically with the care of the newborn. The Premature Infant Activity Schedule (PIAS) was developed by Chamorro, Davis, Green and Kramer (1973), to measure the specific amounts of handling given to the preterm infant in two programs of tactile stimulation. Both the validity and reliability of this tool have been established. Validity was tested by comparing the tool, which utilizes time-sampling methodology, to a continuous observation of the same situation. The median percentage of agreement using the two methods was .90 which falls within acceptable limits (Kerlinger, 1973). The interobserver reliability, i.e. the percentage of agreement on each variable by two observers, was .94 and the intraobserver reliability, established by having an observer score activities recorded on videotape and played back on two occasions, 24 hours apart was .98. This tool would have been ideal if the present study had taken place in a convalescent nursery but unfortunately it did not include many of the nursing activities crucial to the care of the critically ill neonate.

The second tool was developed by Meilicke and Mucha (1971) for a time and motion study of nursing activities in a neonatal intensive care unit. It consisted of a list of major categories of nursing care, which were further delineated by the addition of various descriptors. Since many of the categories included administrative and recording tasks, not directly related to the handling of the infant, nine categories were chosen for inclusion in the present study. These categories were hygiene, positioning, pulmonary care, special procedures, blood sampling,

x-rays, medications, tender loving care (TLC) and a miscellaneous category for any procedure which did not appear on the list. For the nine categories of nursing care, the following definitions apply.

Hygiene is the cleansing of all or part of the infant's body and/or his immediate environment.

Positioning includes turning the infant's body, placement or support of the limbs and restraining the infant by holding or securing any part of the body.

Pulmonary care refers to any action which improves the effectiveness of the infant's ventilation including postural drainage, chest physiotherapy, instillation and suction of the airway, stimulation, bagging and the adjustment of the endotracheal tube or ventilator tubing.

Special procedures are defined as those nursing activities which may be considered therapeutic in that they assist in the monitoring, diagnosis or treatment of the infant's condition. They include taking vital signs, inserting an intravenous or nasogastric tube, collecting a specimen and assisting a doctor with procedures such as a lumbar puncture or the insertion of chest tubes.

Blood sampling refers to the collection of a specimen of the infants blood by venipuncture, heel prick or withdrawal from an umbilical catheter.

An x-ray refers to assisting with obtaining a roentgenogram while the infant remains on an overhead warmer bed.

Medication refers to the administration of any drug via the oral, rectal, intramuscular, intravenous or intra-arterial route.

Tender loving care is defined as the stroking of any part of the infants body with the hands of the caregiver. It also includes holding a soother in the infant's mouth.

In addition to the categories of nursing care and the descriptors, lists of infant behavioral responses and personnel who might handle the baby were included. The complete instrument may be found in Appendix II.

Because of the exploratory nature of the research, continuous observation was considered preferable to time-sampling methodology. Continuous observation captures both the patterning and tempo of the events being observed (Chamorro, et al., 1973), and therefore yields richer information about the phenomenon under study.

Data Collection

Data collection took place over a fourteen week period from October 1, 1979, to January 25, 1980. All observations and recordings were made by the investigator. Each study required twenty four hours of observation separated into two twelve hour periods on consecutive days. In addition, two to three hours were required to set up, dismantle and calibrate equipment. Although it was rare for more than one study to occur in a week, the prolonged observation periods may have altered the reliability of the method.

Reliability refers to "the accuracy or precision of the measuring instrument" (Kerlinger, 1973, p. 443). Interobserver reliability was not determined for the observation tool since the same person collected data throughout the study. A twelve hour pilot study was performed to familiarize the observer with the use of the tool and the recording sheets.

The twelve hour duration of the observation periods led to fatigue and diminished concentration on the part of the observer, particularly when studies occurred during the night. Short rest breaks were taken at a time when handling was considered unlikely to occur, such as between regularly scheduled procedures. It is conceivable, however, that some observations might have been missed during these periods. If the observer was required to be away from the bedside for longer than a few minutes, the unit research nurse or a post graduate nursing student, who had been trained in the use of the tool, continued to make observations during that time. Any of these three factors could have altered the reliability of the measurement.

The validity of the continuous observation tool is unknown and was not investigated in the present study.

Data Analysis

All categories, descriptors, and personnel included in the nursing observation tool were given a code to facilitate recordings by the observer (see Appendix II). An observation form was also developed for use with the master coding sheet (Appendix III).

Following collection of all the data, they were analysed with the assistance of a medical statistician. The four types of analysis used in this study were rank order, frequency, difference between means and correlation.

Rank ordering is the first step in the tabulation of data and involves the arrangement of scores in order of size (Glass & Stanley, 1970). Nursing care was ranked in order of those procedures which took the greatest amount of time, to those which took the least.

Frequency refers to the number of times an event occurs (Glass & Stanley, 1970). Frequency distributions were used to describe the number of times infants were handled during the study periods.

In reference to the equivalent time-samples design, Campbell and Stanley (1963) state "significance of the difference between the means of two sets of measures is employed" (p. 43). Means and standard deviations were calculated for all measures of handling and physiological values during the experimental and control periods. The level of significance chosen was .05 and the significance of the difference between means was determined by the use of paired t tests. If it could be assumed that the ten babies in this research were representative of a larger population of all such babies, then the differences observed in this study would be expected to be found in the larger population.

Regression equations were utilized to explore relationships between handling and physiologic measures and also to test the

reliability of the continuous PO_2 monitor. The correlation coefficients (Pearson's r) so obtained were tested for significance using the following formula:

$$t = r \sqrt{\frac{n-2}{1-r^2}}$$

A probability value (p) of less than .05 was again chosen as the level of significance.

Methodological Limitations

Because of the fairly stringent criteria required for the study population, random selection of subjects would have extended the study period beyond the time available to the researcher. The group studied therefore constitutes a specific population rather than a random sample of a wider population and limits the generalizability of the results to other infants. Further limitations are imposed by the lack of complete random assignment to experimental and control situations necessitated by the clinical condition of some of the infants.

Although the sample was small ($n = 10$), each infant was studied for a total of 24 hours. The length of the study periods therefore allowed a large number of observations to be made and provided a great deal of data regarding physiological and behavioral responses to handling.

C H A P T E R I V

Results of the Study

The results obtained suggest that while the duration and frequency of handling were not different during the experimental and control periods, and showed no association with the duration of changes in physiologic parameters, specific types of nursing care were related to the incidence of hypoxia, hyperoxia, and increased intracranial pressure.

The Study Population

Ten infants meeting all study criteria were admitted to the unit over a fourteen week period. Nine of the infants were born at the Royal Alexandra Hospital, and one was transported by ambulance from Barrhead, Alberta. Nine infants had a diagnosis of hyaline membrane disease based on clinical and radiologic criteria. The tenth infant suffered from aspiration pneumonia and acute hypovolemia.

There were three female and seven male infants. Their birth weights ranged from 960 to 2000 grams with a mean of 1550 gm. Their gestational ages ranged from 26 to 37 weeks, with a mean of 32 weeks (Table II).

Frequency and Duration of Handling

The frequency and duration of handling were not significantly different during the experimental and control

Table II Demographic Characteristics of Study Subjects

Subject	Gender	Birthweight (grams)	Gestational Age (Weeks)	Dates	Dubowitz	Diagnosis
1	M	1460	32	33	HMD ^a	interstitial emphysema
2	F	1720	31	31	HMD, PDA ^b	apnea
3	M	1760	36	?	Aspiration pneumonia,	acute hypovolemia
4	M	1870	37	34+	HMD,	pneumothorax
5	F	1060	32	32	HMD,	intracranial hemorrhage
6	M	1670	30	34+	HMD	
7	M	2000	32	32+	HMD	
8	M	1940	33	33+	HMD	
9	F	960	26	28	HMD,	interstitial emphysema, pneumothoraces
10	M	1150	29	30	HMD	

^a Hyaline membrane disease

^b Patent ductus arteriosus

periods. Babies were handled an average of 54 times (range 41 to 79 times) while they were receiving pancuronium and 50 times (range 33 to 68 times) while they were not. Disturbances occurred an average of four to five times an hour over the 24 hour period. The babies were handled an average of 130 minutes (range 106 to 164 minutes) during pancuronium and 135 minutes (range 80 to 188 minutes) during the control period. The mean duration of disturbance was 2.41 minutes on pancuronium compared to 2.70 minutes during the control period (Table III).

Nature of Handling

The nursing observations for the ten study subjects were grouped according to their similarities. Ten distinct categories of nursing care were determined, and were ranked according to the frequency of their occurrence (Table IV).

Airway suctioning which included instillation of normal saline, endotracheal and oral suction was the most time consuming procedure, with each infant receiving an average of 30 minutes of suctioning every 12 hours. Suctioning occupied 21.66% of the nurses' time during the control period, and 24.06% when the infant was receiving pancuronium.

The handling of equipment ranked closely behind suctioning. This category included such nursing activities as applying or changing chest leads, inserting an intravenous, calibrating a blood pressure transducer and applying a probe for continuous monitoring of temperature. Only those procedures which involved physical contact with the infant were included.

Table III Duration and Frequency of Handling Under
Experimental and Control Conditions

Handling Subject	Pancuronium		Control	
	Duration (minutes/12 hours)	Frequency	Duration (minutes/12 hours)	Frequency
1	120	45	188	49
2	164	44	116	36
3	118	41	90	33
4	157	44	162	50
5	106	50	162	59
6	159	77	170	66
7	108	51	130	59
8	116	50	80	37
9	133	79	128	52
10	116	61	127	68
Mean	129.7	54.2	135.3	50.9
Standard Deviation	22.2	13.7	35.0	12.4

Table IV Categories of Handling Ranked According
To Duration and Percentage of Time
Spent on Each

Pancuronium		
Handling	Time spent (minutes)	Percentage of total time
Suctioning	312	24.06
Handling equipment	247	19.04
Vital Signs	175	13.49
Blood sampling	172	13.26
Hygiene	91	7.02
Medications	78	6.01
Physical exam	63	4.86
T.L.C.	59	4.55
Weighing	42	3.24
Diagnostic procedures	34	2.62
Physiotherapy	24	1.85
All handling	1297	100.00
Control		
Handling	Time spent (minutes)	Percentage of total time
Suctioning	293	21.66
Handling equipment	289	21.36
Blood sampling	187	13.82
Vital signs	173	12.79
T.L.C.	100	7.39
Hygiene	95	7.02
Physical exam	74	5.47
Weighing	54	3.99
Medications	45	3.33
Diagnostic procedures	37	2.73
Physiotherapy	6	0.44
All handling	1353	100.00

This took up 21.36% of the nurses' time during the control period and 19.04% during pancuronium.

Taking vital signs was another frequently performed nursing task comprising 12.79% (control) to 13.49% (pancuronium) of the total care. Vital signs included taking a rectal temperature, determining the apical heart rate with a stethoscope and obtaining a blood pressure using Doppler equipment. Counting the infant's respiratory rate was not included unless the nurse placed a hand on the infant's chest.

Approximately 13% of the infant's care consisted of obtaining blood samples. Arterial blood gas samples, drawn from the umbilical artery catheter, were the most frequent samples required followed by heel stick procedures for Dextrostix. Other heel stick or catheter samples for bilirubin, blood sugar or electrolytes usually occurred only once per shift.

Only 7% of care was concerned with the infant's hygiene, with the same percentage of time being spent under experimental and control conditions. This similarity is surprising in light of the fact that eye care and bladder expression, which are required frequently by the baby who is paralysed, were included in this category. Possibly these procedures were not carried out frequently enough.

The effects of paralysis are reflected, however, by the disparity between the two periods in the length of time spent giving medications and soothing the infant (giving TLC). Medication administration is doubled (from three to six percent) during the experimental period presumably by the repeated

administration (every 60 to 90 minutes) of pancuronium. The time spent stroking the infant is doubled (7.39% compared to 4.5%) during the control period, when the infant is able to cry and to move.

Physical examination which included auscultation, percussion and palpation was placed in a separate category since it tended to be performed by medical staff rather than nurses. Physical examinations occurred sporadically, but ranked seventh during both experimental and control periods accounting for 4.86% (experimental) and 5.47% (control) of the total handling the infants received.

Weighing and diagnostic procedures, while accounting for only about five percent of handling, were considered separately because they were associated with both hypoxia and hyperoxia. Diagnostic procedures performed during the study included roentgenograms (x-rays), lumbar punctures (LP's) and electrocardiograms (ECG's).

Physiotherapy was required by only one infant and accounted for less than two percent of the handling described.

Relationships Between Pancuronium and Physiological Measures

No differences were found between mean heart rate and arterial blood pressure during the experimental and control periods. The mean heart rate was 147.2 beats per minute (range 136 to 165 beats per minute) during pancuronium and 146.5 beats per minute (range 130 to 167 beats per minute) during the control period. The mean blood pressure was 41.5 torr (range 33

to 59 torr) during pancuronium and 43.2 torr (range 32 to 66 torr) during the control period (Table V).

Significant differences did occur, however, in the incidence of hypoxia, hyperoxia, and increased intracranial pressure during the control and experimental conditions. The mean duration of these events was compared for each individual subject on and off pancuronium.

The means duration of hypoxia ($PO_2 < 50$ torr) was 56.1 minutes per 12 hours in the control period and 23.6 minutes per 12 hours during pancuronium ($t(9) = -4.53$, $p < .01$). The mean duration of hyperoxia ($PO_2 > 70$ torr) was 92.5 minutes per 12 hours in the control group and 13 minutes per 12 hours during pancuronium ($t(9) = -3.45$, $p < .01$) (Table VI).

Mean intracranial pressure (ICP) was 10 cm H_2O or greater above baseline for 58.8 minutes per 12 hours during the control period and 6.7 minutes per 12 hours during pancuronium ($t(9) = -4.08$, $p < .01$). Spikes indicating an intracranial pressure value of greater than 25 cm H_2O occurred an average of 24.4 times per 12 hours during the control period and 1.6 times per 12 hours during pancuronium ($t(9) = -2.31$, $p < .05$) (Table VII).

Relationships Between Handling and Physiological Measures

Correlations were determined between the frequency and duration of handling and the duration of changes in the physiological measures. None of the correlations was significant when the Pearson's r was converted to a t - value.

Table V Mean Heart Rate and Arterial Blood Pressure
Under Experimental and Control Conditions

Subject	Heart Rate (Beats per minute)		Blood Pressure (torr)	
	Pancuronium	Control	Pancuronium	Control
1	141	138	41	43
2	139	158	35	40
3	150	138	35	32
4	165	153	39	66
5	157	167	33	35
6	136	130	59	55
7	136	143	54	43
8	154	144	41	48
9	147	143	44	36
10	147	151	34	34
Mean	147.2	146.5	41.5	43.2
Standard Deviation	9.6	10.9	8.7	10.7

Table VI Duration of Hypoxia and Hyperoxia Under Experimental and Control Conditions

Subject	Hypoxia (minutes/12 hours)		Hyperoxia (minutes/12 hours)	
	Pancuronium	Control	Pancuronium	Control
1	19	60	4	59
2	16	68	0	227.5
3	19	69	26	148
4	50.5	61	26	194.5
5	15	34.5	35	45
6	0	37	12.5	101.5
7	35	121.5	6.5	42.5
8	36	71.5	10	66
9	37.5	12.5	5	20.5
10	8	26	5	20.5
Mean	23.6	56.1	13.0	92.5
Standard Deviation	15.5	30.7	11.8	73.6

Table VII Changes in Intracranial Pressure Under
Experimental and Control Conditions

Subject	Intracranial Pressure			
	10 cm H ₂ O above baseline		#Spikes	25 cm H ₂ O
	Pancuronium	Control	Pancuronium	Control
1	2	46	8	17
2	23	124	0	104
3	13	82	3	58
4	5	50	1	9
5	9	22	2	2
6	6	143	1	39
7	3	30	1	6
8	0	39	0	4
9	3	8	0	0
10	3	44	0	5
Mean	6.7	58.8	1.6	24.4
Standard Deviation	6.8	44.0	2.5	33.7

This may have been due to the fact that seven of the ten study subjects received sedative medication during the control period (Table VIII). Sedation lowers the infants level of arousal and decreases the incidence of crying thereby altering the response to crying.

When relationships between the nature of handling and physiologic changes were examined using the same form of analysis, however, eight correlations were found to be significant. The duration of hypoxia was associated with diagnostic procedures ($t(9) = 3.44$, $p < .001$) when the infants were receiving pancuronium, and with suctioning ($t(9) = 2.84$, $p < .02$) and weighing ($t(9) = 2.12$, $p < .05$) when they were not. Hyperoxia was associated with weighing the infants ($t(9) = 2.30$, $p < .02$) during pancuronium and with hygiene ($t(9) = 2.36$, $p < .02$) and TLC ($t(9) = 1.86$, $p < .05$) during the control period. Intracranial pressure changes greater than 10 cm H₂O above baseline were related to vital signs ($t(9) = 2.23$, $p < .05$) and TLC ($t(9) = 2.68$, $p < .02$) during pancuronium. Throughout the control period, increases in intracranial pressure occurred during crying but were unrelated to any specific type of handling (Table IX).

Additional Findings

During the course of the investigation, certain observations led the researcher to ask the following questions.

1. Is there a difference in the infant's temperature when he is receiving pancuronium?

Table VIII Sedative Medications Administered
During the Control Period

Subject	Medication	Dosage	Frequency
2	Chloral hydrate	40 mg.	x2
5	Phenobarbital	15 mg.	x2
6	Chloral hydrate	40 mg.	x1
7	Chloral hydrate	40 mg.	x2
8	Chloral hydrate	40 mg.	x1
9	Phenobarbital	10 mg.	x2
10	Chloral hydrate	25 mg.	x1

Table IX Nursing Procedures Which Were Significantly
 Related to Changes in Physiologic Parameters

Physiologic Change (Duration)	Nursing Procedure (Duration)	Pancuronium (P) or Control (C)	Pearsons r	t Value	Signi- fiance
Hypoxia	Diagnostic procedures	P	.77	3.44	p < .001
	Suctioning	C	.71	2.84	p < .02
	Weighing	C	.60	2.12	p < .05
Hyperoxia	Weighing	P	.63	2.30	p < .02
	Hygiene	C	.64	2.36	p < .02
	T.L.C.	C	.55	1.86	p < .05
Increased Intracranial Pressure	Vital signs	P	.62	2.23	p < .05
	T.L.C.	P	.69	2.68	p < .02

2. Is there a relationship between changes in physiological parameters which is not associated with either pancuronium or handling?
3. Is the infant's birthweight associated with changes in physiological parameters?

Many of the infants were noted to have lower rectal and skin temperatures during the administration of pancuronium. When mean differences in temperature were compared, however, the t - values did not reach the .05 level of significance (Table X).

The second question arose from the observation that physiologic values such as heart rate and blood pressure often varied in direct or inverse proportion to changes in other values. The relationships among hypoxia, hyperoxia and intracranial pressure were therefore examined. Hyperoxia and increased intracranial pressure were related ($r = .65$, $t(9) = 2.41$, $p < .02$) during the control period but not when the infants were receiving pancuronium. An appropriate level of significance (.05) was not reached with the other correlations.

The third question was posed on the assumption that smaller infants would be more acutely ill, be handled more frequently and therefore show longer periods of hypoxia than the larger babies in the study. In fact, the opposite was found to be the case, since birthweight was positively correlated with hypoxia ($r = .83$, $t(9) = 4.22$, $p < .001$). The larger the infant, the more hypoxia he experienced.

Table X Rectal and Skin Temperatures of Infants
During Experimental and Control Periods

Subject	Mean Rectal Temperature (degrees Centigrade)		Mean Skin Temperature (degrees Centigrade)	
	Pancuronium	Control	Pancuronium	Control
1	37.07	37.20	37.11	36.63
2	36.40	37.17	36.59	36.84
3	36.93	37.00	36.42	36.29
4	36.93	37.13	36.40	36.74
5	36.66	36.70	37.25	37.80
6	37.00	37.30	36.38	36.55
7	36.83	36.70	36.78	36.89
8	37.00	37.07	37.04	36.77
9	36.86	36.83	37.12 ^a	36.90 ^a
10	37.10	36.80	36.42	36.23
Mean	36.87	36.99	36.75	36.76
Standard Deviation	.21	.22	.35	.43

^a These readings were obtained from a rectal probe

Reliability of PO₂ Monitoring

Finally, the correlation between the PO₂ values registered by the continuous monitor and those obtained from arterial blood gas samples was determined. The Pearson's r value obtained was .93 indicating that this form of monitoring was reliable.

The drift of the PO₂ monitor was calculated for the 12 hour study period using the formula:

$$IVO_2 - PaO_2 = \frac{\Delta O_2}{\text{time in minutes since last calibration}} \times 60 = \text{Drift in mm Hg/hour}$$

The average drift for all infants monitored over all study periods was 0.14 mm Hg per hour, further illustrating the reliability of this form of monitoring.

C H A P T E R V

Discussion, Conclusions and Recommendations

In this final chapter, the results of the study will be discussed and conclusions drawn. Suggestions will be made, based on the findings, for the modification of existing nursing procedures. The limitations of the study will be presented and application of the SDS model will be discussed. Lastly, implications for future research and for nursing will be detailed.

Discussion of Findings

The results of the study suggested that certain types of handling were related to deviations in PO_2 and intracranial pressure beyond normal physiological bounds. These responses were modified or eradicated by the use of muscle relaxant medication in the critically ill preterm neonate.

Since the frequency and duration of handling of the neonate were not different during the experimental and control periods, the data will be discussed in relation to the entire study period. The mean number of contacts per infant was 105 in 24 hours (range 74 to 143), a figure slightly lower than the 132 contacts per 24 hours described by Korones (1976). The mean duration of contact per baby, however, was higher in the present study, being 265 minutes per baby per 24 hours, compared to 238 minutes per baby per 24 hours in Korones' study (1976). The similarity of the values suggests that the observation

tool may be reliable. It is evident though that technological advances in NICU, such as continuous monitoring of vital signs and PO_2 , have done little to diminish the frequency and duration of disturbance the infant receives.

The time consuming nature of the equipment factor is further verified by the data illustrating that 19 to 21% of the handling of the infants was concerned with the adjustment of equipment. Whether this indicates that equipment actually needs frequent adjustment and calibration, or whether, as nurses, we do not yet trust equipment to lighten our workload is unknown.

A further 21 to 24% of handling was related to airway suctioning. Since suctioning is clearly related to hypoxia when the infants are not receiving pancuronium, nurses need to consider ways in which the procedure could be modified to maintain a more stable PO_2 . Huch and Huch (1976) advocate increasing the FiO_2 for one to two minutes prior to suctioning. This increases the PO_2 by 10 to 20% thereby ensuring that the fall in PO_2 , when it occurs does not reach a dangerous level. Each episode of suctioning that occurred during the control periods of the present study was examined individually. In almost every instance FiO_2 was increased prior to suction yet prolonged periods of hypoxia persisted, followed by rebounds of hyperoxia.

Approximately 13% of the infants' care was related to obtaining blood samples, the majority of those samples being arterial blood gases (ABG). While this may appear to be an inordinate percentage of total care, it involves only 16 minutes

over a 12 hour period. Considering the acuity of illness of the infants studied, this amount of time does not seem inappropriate.

Weighing the infant was also associated with hypoxia during the control period. This phenomenon may be explained by the removal of infants from the ventilator to place them on the scale. The decision as to whether the infant receives manual ventilation during this time is left to the discretion of the nurse. The nurse is aware that an infant on pancuronium is unable to breathe spontaneously, therefore, she is more likely to manually ventilate the infant, thereby maintaining a stable PO_2 . The data suggest that infants should be attached to an oxygen source if not ventilated by resuscitation bag during weighing. Since infants became hyperoxic during weighing when they were paralysed, however, that suggests that manual ventilation was, at times, overly vigorous. Keeping a close watch on the PO_2 monitor during bagging would appear to be an important nursing responsibility in maintaining stability of the infant's condition.

When infants were receiving pancuronium, the only type of handling that correlated with hypoxia was diagnostic procedures. In all instances this involved a chest x-ray. These tended to be prolonged procedures, lasting about ten minutes and involving a great deal of handling of the infant and several changes in position. During such times, endotracheal tubes frequently became kinked or disconnected from the ventilator. Because the babies were paralysed, they were unable to breathe spontaneously. Two of the infants had a marked fall in temperature during the procedures possibly resulting from the movement of the overhead

radiant heat source away from the bed to facilitate placement of the x-ray machine. Placing the infants on cool x-ray plates could also have contributed to conductive heat loss. Close observation of the position and connections of tubing should decrease the incidence of inadvertent kinking or disconnection. Checking the infant's rectal and skin temperatures immediately following an x-ray and ensuring that x-ray plates are wrapped in bubble plastic or a diaper may be advisable precautions in averting cold stress.

The observed relationships between hyperoxia, hygiene and TLC when infants were not paralysed are more difficult to interpret. If both hygiene and TLC are viewed as comfort measures, then presumably the infant's level of arousal is lowered and he may stop crying or fall asleep. This should in turn decrease the infant's oxygen consumption and increase his PO_2 even with the same inspired oxygen concentration. In addition, settling the infant should decrease shunting and ventilation/perfusion abnormalities secondary to crying.

Increases in intracranial pressure related to the taking of vital signs were probably caused by holding the infant's feet in the air to insert a rectal thermometer. Raising the feet causes increased cerebral blood flow thereby increasing intracranial pressure. Possibly the relationship between vital signs and raised intracranial pressure does not hold true during the control period because the normal muscle tone of the diaphragm prevents the pressure of the abdominal contents on the thoracic cavity maintaining normal blood flow and ICP.

The relationship between increased ICP and TLC is difficult to interpret logically. On two occasions an abrupt rise in ICP was noted when infants first heard their mother's voice or had physical contact with her. One possible explanation is that increased ICP may be a physiologic response to pleasurable sensation, exaggerated in the paralysed infant because he has no other outlet for expression.

The relationship found between hyperoxia and increased intracranial pressure is probably associated with the manual ventilation of infants during procedures such as weighing or in response to hypoxic episodes. Vigorous manual ventilation can increase both ventilatory rate and peak inspiratory pressure, leading to hyperoxia and increased ICP, through an increase in central venous pressure.

The higher the infant's birthweight, the greater the duration of hypoxia during the study period. Since heavier babies were also older, it seems likely that they had attained a higher level of physical and motor development than the smaller, younger infants. Their increased muscular development may have contributed to struggling in response to handling. These babies showed more spontaneous movements, cried more frequently and persistently, and tended to be more difficult to soothe.

Conclusions

The findings of the study have provided some answers to the four questions posed at the outset. The nature, duration and frequency of nursing care of the critically ill preterm neonate

have been described, and no differences were found during the administration of pancuronium and control periods. The infants studied did experience periods of hypoxia, hyperoxia and increased intracranial pressure in response to "routine" handling and care. The periods of fluctuation beyond physiological bounds were significantly reduced by the administration of pancuronium.

Based on these findings, the following tentative conclusions may be drawn:

1. nursing care does not differ in nature, duration or frequency when an infant is paralysed;
2. nursing care influences the physiological stability of the critically ill preterm neonate, whether or not he is paralysed; and
3. pharmacologically induced skeletal muscle relaxation reduces the potentially harmful physiological effects of handling of the preterm neonate.

Limitations of the Study

In order to fully evaluate the response of the preterm neonate to nursing care, a larger, randomly selected sample of infants would be required. The findings suggest that the replication of the present study with infants of different birth weights, gestational ages and diagnoses, who are admitted to other neonatal intensive care units would be worthwhile to determine whether the conclusions reached are applicable to a wider population.

The SDS model for nursing practice might have restricted

the investigator's perception of the overall problem by focusing too specifically on stress as a change agent for the client. Other conceptual frameworks, could have suggested a different approach to the study.

It is hoped, however, that the study will suggest to nurses that their care does make a difference to the infant's condition and will provoke further investigations into methods of modifying care to improve the outcome for the patient.

The Conceptual Framework

The systems-developmental stress (SDS) model of nursing care, as outlined in Chapter I, has been applied and supported in the present research. The handling necessitated by care in a neonatal intensive care unit was postulated to be a stressor to the preterm infant. This was demonstrated by the stress state created in the infant by hypoxia, hyperoxia and increased intracranial pressure. Adaptation to the stressor in the form of a decreased incidence of fluctuation in physiologic parameters was aided by the administration of pancuronium. Stressed change, the final step in the stress process, can only be evaluated on the basis of long-term follow-up, which was beyond the scope of the present study.

Implications for Further Research

Further research suggested by the present study falls into two major categories: research into the effects of muscle relaxation on the neonate, and research on the effects of nursing

care.

Two questions arise in relation to the future use of pancuronium bromide or other drugs which induce skeletal muscle relaxation. Both questions relate to the issue of cost vs benefit, i.e. are the risks associated with the administration of the drug smaller than the benefits gained by the infant?

It would be useful for clinicians to know whether there are any long term effects, for example, on gross motor function, related to the use of muscle relaxation in the neonatal period. The first use of pancuronium in the neonate, as an adjunct to anaesthesia, was reported in 1975 by Bennett and co-workers. To the author's knowledge, no long term studies have been undertaken.

The second question relates to the effects of paralysis on the development of parent-infant attachment. Klaus and Kennell (1975) state "you can't love a dishrag" (p. 14) and stress the importance of the infant's response in forming a close bond with the parents. Visiting patterns of the parents of paralysed infants, as well as their participation in tactile stimulation of the baby, are important areas for investigation.

Finally, it is necessary to ask whether the hypoxia, hyperoxia and increased intracranial pressure which were shown in this study to be modified by the administration of pancuronium, could be diminished by other, less drastic methods such as the alteration of nursing care. Those types of nursing care which were shown to be related to alterations in physiological parameters, namely diagnostic procedures,

suctioning, weighing, hygiene, vital signs and tender loving care could be investigated and modified to prevent undesirable changes in the homeostatic state of the infant.

Implications for Nursing

In its broadest scope, the present study may be seen to have a number of implications for both the practice and the profession of nursing. The basic design of the research and its emphasis upon the study of nursing activities contributes to the growing body of knowledge regarding what nurses do. By increasing our understanding of the implications of what we do, nurses are coming to define more clearly the unique contributing functions of the nurse. Such knowledge is integral to the development of a profession and the improvement of nursing care.

Exploration of the relationships between nursing care and the physiological state of the infant should help nurses, particularly those involved in providing direct care, to increase their awareness of the impact they may have on the patient.

The present research also illustrates one way in which a conceptual framework for nursing practice may be operationalized. The framework was useful for guiding the planning and conduct of the research and the interpretation of the results.

The study also stands as an example of multidisciplinary research. The influence of a medical therapy on the effects of nursing care was seen to be an important subject for investigation, employing both the knowledge and skills of the

professionals from the two disciplines.

Lastly, the research constitutes a beginning response to Silverman's challenge, quoted in Chapter 1. Seemingly "routine" nursing procedures have been subjected to critical testing and recommendations, based on the findings, have been made for the improvement of care for the critically ill preterm neonate.

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APPENDIX I

CONSENT FOR MUSCLE RELAXATION STUDY

NAME OF PATIENT _____ DATE _____ TIME _____

I, _____ bearing the relationship of _____
to this baby, hereby consent to allow Dr. Finer, Dr. Stewart, or their associates
to perform the following study.

Dr. Stewart, Dr. Finer has explained the purpose of this study.

PURPOSE

This study is designed to determine the effects of muscle relaxation on critically ill newborns. It is hoped that by relaxing the infant's muscles, we can prevent the struggling which often results from handling these babies and thereby improve their oxygenation.

The study will involve observation of the infant's response to handling for a total of 24 hours. During one 12 hour period, the baby will be given a drug (Pavulon) to achieve muscle relaxation. During another 12 hour period the drug will not be given. Throughout both study periods the infant's heart rate and blood pressure will be monitored. In addition, the infant's intracranial pressure will be monitored through a device which sits on the baby's soft spot or fontanel. This will necessitate the shaving of a small area of the baby's head. The oxygen level will be continuously monitored by a device in the umbilical artery catheter which is already in place.

The purpose of this study is to determine the effects of muscle relaxation on the oxygenation of the critically ill newborn. It is hoped that the findings will help us to improve the care of these babies.

Parents are invited to be in attendance at the time the study is being done and the results of the study will be discussed in detail with the parents if they so desire.

PARENT(S)

WITNESS

PARENT(S)

WITNESS

APPENDIX II

PERSONNEL:

CATEGORY

(RN) Nurse	(RT) Respiratory Therapist	(MO) Mother
(MD) Doctor	(PT) Physiotherapist	(FA) Father
(OT) Other (specify)	(XY) X-Ray Technician	(SI) Sibling

PROCEDURE:

(HY) HYGIENE	(1) Bathing	(5) Cord Care
	(2) Eye Care	(6) Buttocks Care
	(3) Mouth Care	(includes diaper changing)
	(4) Nasal Care	(7) Changing Bed Linen
(PO) POSITIONING	(1) Change	(2) Restrain
(PC) PULMONARY CARE	(1) Postural Drainage	(5) ETT Suction
	(2) Chest Physio	(6) Stimulation
	(3) Oral/Nasal Suction	(7) Bagging
	(4) Instillation	(8) Adjusting Equipment (contact with baby)
(SP) SPECIAL PROCEDURES	(1) Vital Signs	(5) Lumbar Puncture
	(2) N/G Tube	(6) Cutdown/Scalp Vein
	(3) Intubation	(7) Chest Tubes
	(4) Dressing	(8) Specimen Collection

...continued

PROCEDURE:
...continued

	(BS)	BLOOD SAMPLING	(1) (2)	Venipuncture Heelstick	(3)	Catheter Sample
(XR)	X-RAY		(1) Chest		(2)	Abdomen
(ME)	MEDICATION		(1) Oral (2) Rectal		(3) (4)	IV IM
(TLC)	TENDER LOVING CARE		(1) Lifting (2) Stroking		(3)	Moving Limbs
(MI)	MISCELLANEOUS		(1) Specify			

INFANT'S ACTION:

(CRY)	CRYING	(1) (2)	Began Continued	(3)	Ceased
(MOV)	MOVEMENT	(1) (2)	Increased No Change	(3)	Decreased
(OTH)	OTHER	(1)	Specify		

APPENDIX III

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